

Notice of Allowability	Application No.	Applicant(s)	
	10/500,018	MINAMITAKE ET AL	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendment received 20 June 2006.
2. ☒ The allowed claim(s) is/are 24-51.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|---|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Christopher Nichols on June 30, 2006.

The application has been amended as follows:

In the claims:

24. (currently amended) A method for producing a protected peptide fragment, wherein at least one amino acid or non-amino acid is modified as represented by the formula - A(R)-_n (wherein A represents an amino acid or a non-amino acid, and R represents a substituent bound to a side chain of A which is introduced for modification), which comprises:

(a) preparing, on a weak acid-cleavable resin, a peptide main chain sequence of a peptide fragment which has a desired sequence comprising amino acids ~~and/or~~ or amino acids and non-amino acids, wherein one or more reactive functional groups in a side chain of an amino acid or a non-amino acid which may cause an undesirable side reaction during preparation of a peptide fragment are protected with a protecting group, the one or more reactive functional groups being selected from the group consisting of a hydroxyl group, an amino group, a guanidino group, an imidazolyl group, an indolyl

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group, a mercapto group and a carboxyl group, in a side chain of an amino acid or a non-amino acid,

(b) deprotecting the protecting group of at least one reactive functional group in the side chain of an amino acid or a non-amino acid A which is to be modified with a substituent R without cleaving the peptide fragment from the weak acid-cleavable acid-cleavable resin,

(c) modifying the deprotected side chain with a substituent R, and

(d) cleaving the peptide fragment from the weak acid-cleavable resin under weakly acidic conditions ~~without elimination of the protecting group in the peptide fragment.~~

The following is an examiner's statement of reasons for allowance: claims 24-51 are drawn to a method for producing a protected peptide fragment comprising (a) preparing on a weak acid-cleavable resin, a peptide sequence of a peptide fragment which has a desired sequence comprising amino acids or amino acids and non-amino acids, wherein one or more reactive functional groups in a side chain of an amino acid or a non-amino acid are protected with a protecting group, (b) deprotecting the protecting group of at least one reactive functional group in the side chain of an amino acid or a non-amino acid, (c) modifying the deprotected side chain with a substituent R, and (d) cleaving the peptide fragment from the weak acid-cleavable resin under weakly acidic conditions. The novel concept of the instant invention is the modification of a side chain on the peptide fragment, without undesirable side reactions from other functional

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groups, while still attached to the resin support. The modified peptide fragment is subsequently cleaved from the resin with the other functional groups on the modified peptide fragment still protected. The claims clearly define the invention and are free of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 24-51 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 30, 2006

A handwritten signature in black ink, reading "Karen Cochrane Carlson" followed by a stylized "Ph.D." or similar initials.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER